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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Robert A. Ashley Examiner: Unassigned  
Serial No.: 10/757,656 Group Art Unit: 1617  
Confirmation No: 3939 Docket: 512-53 DIV  
Filed: January 14, 2004 Dated: July 19, 2006  
For: METHODS OF TREATING  
ACNE

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

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**COMMUNICATION**

Sir:

Accompanying the present Communication is a package insert for the pharmaceutical Oracea<sup>TM</sup>, marketed by CollaGenex Pharmaceuticals, Inc. Oracea<sup>TM</sup> is a 40 mg capsule of controlled-release doxycycline. On page 1, 1<sup>st</sup> column, last paragraph, of the package insert, the following is stated:

ORACEA is indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients. No meaningful effect was demonstrated for generalized erythema (redness) of rosacea. ORACEA has not been evaluated for the treatment of the erythematous, telangiectatic, or ocular components of rosacea.

Although the treatment of erythema with 40 mg of doxycycline was not evaluated to the level required by the FDA, a therapeutic effect was shown for erythema. For example, enclosed is a copy of a poster entitled "Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Trial Results Evaluating the Effects of 40 mg Doxycycline Monohydrate Controlled-Release Capsules in the Treatment of Rosacea." This poster was presented on March 4, 2006 at the American Academy of Dermatology meeting in San Francisco, CA.

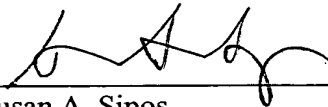
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The poster details the results of two, phase III, parallel-group, multicenter, randomized, double-blind, placebo-controlled, 16-week trials that evaluate the efficacy and safety of 40 mg, controlled-release doxycycline monohydrate administered once daily versus placebo for the treatment of adult rosacea.

In the poster, in the "Efficacy Results" section on the third page, the results of "Erythema Scores" are set forth. In one of the trials, "study 301," the reduction from baseline in the mean total erythema score was said to be significantly greater at week 16 for the treated group when compared with the placebo group. The decrease in total erythema score was said to become statistically significant by week 6 for the treated group when compared to the placebo group. There was a continual progressive reduction in the total erythema score through week 16.

In the other trial, "study 302," the change from baseline in the total erythema score was said to indicate that facial redness improved in patients in the treated group versus the placebo group. However, the between group difference was said not to be statistically significant.

Respectfully submitted,



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